

REMARKS

1. Preliminary Remarks

a. Status of the Claims

Claims 1-8, 11, 12, 14, 16-23, and 25 are pending in this application. Claims 1, 5, 6, 11, 16, 17, and 22 are amended; claims 28-33 are new; and claims 2, 7, 18-20, and 25 are canceled. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of this application. Upon entry of the amendments, claims 1, 3-6, 8, 11, 12, 14, 16, 17, 21-23, and 28-33 will be pending and under active consideration.

b. Amendments to the Claims

Support for the amended claims can be found in the application as originally filed as shown in the table below:

| Claim | Location of Support |
|-------|---------------------|
| 1 | ¶¶ 0056 and 0057 |
| 11 | claims 6, 7, and 11 |
| 16 | ¶¶ 0056 and 0057 |
| 17 | ¶ 0029 |
| 22 | ¶¶ 0056 and 0057 |
| 28 | ¶ 0078 |
| 29 | ¶ 0078 |
| 30 | ¶ 0045 |
| 31 | ¶ 0045 |
| 32 | ¶ 0051 |
| 33 | ¶ 0072 |

Additionally, claims 5 and 6 are amended to correct a typographical error.

2. Requirement for Unity of Invention/Election

On pages 2-5 of the Office Action, the Examiner under 35 U.S.C. §§ 121 and 372, and 37 C.F.R. § 1.499 requires Applicant to elect one of the following inventions:

- I. Group I, claims 1-8, 11-12, 14, 22, and 23, drawn to a method for isolating T cells that cross-react with a self-antigen and a foreign antigen;
- II. Group II, claims 16 and 17, drawn to a composition comprising T cells that cross-react with a self-antigen and a foreign antigen;
- III. Group III, claim 18-20, drawn to a method for quantifying the number of T cells in a sample that cross-react with a self antigen and a foreign antigen, and a method for diagnosing or monitoring autoimmune disease comprising quantifying said T cells;

- IV. Group IV, claim 21, drawn to a method for treating an autoimmune disease in a patient comprising administering a composition comprising T cells that cross-react with a self-antigen and a foreign antigen; or
- V. Group V, claim 25, drawn to a method for isolating a nucleic acid encoding a T cell receptor from a T cell specific for a self-antigen and a foreign antigen.

Applicant with traverse elects **Group II**, which is related to claims **16, 17, 28, and 29**. Specifically, Applicant respectfully traverses the Examiner's restriction requirement with regard to Groups I, II, and IV. On page 3 of the Office Action, the Examiner contends that all of the groups listed above lack unity of invention because the claimed subject matter does not make a contribution over the prior art in view of Cirone *et al* (Journal of Medical Virology 2002;68:268-72; "Cirone"), and therefore lack a common special technical feature. Specifically, the Examiner asserts that Cirone teaches a method for producing a T cell composition comprising T cells that are cross-reactive with epitopes of myelin basic protein ("MBP") and herpesvirus-6 ("HHV-6"). Instant Office Action at 3. Applicant respectfully submits that the amended claims have unity of invention, as discussed below.

Claimed inventions have unity of invention as long as they share at least one special technical feature that makes a contribution over the prior art. *See* MPEP § 1850.I. A special technical feature makes a contribution over the prior art if it is novel and requires an inventive step. *See Id.* at § 1850.II. Applicant submits that the subject matter of the amended claims is neither taught nor suggested by Cirone, and that this reference does not provide any way of arriving at the claimed subject matter.

The amended claims are related to T cells that cross-react with a self-antigen and a foreign antigen, where the self-antigen includes residues 96-102 or 93-105 of MBP and the foreign antigen includes residues 4-10 or 1-13 of the HHV-6 U24 protein. In contrast, Cirone does not teach any specific protein of HHV-6, let alone residues 4-10 or 1-13 of HHV-6 U24, nor does this reference teach residues 96-102 or 93-105 of MBP. Moreover, there is no teaching in Cirone that would allow one of skill to arrive at the claimed T cell composition, since Cirone gives no guidance as to which proteins or epitopes of HHV-6 have any significance, or which peptides of MBP, if any, may be significant. Accordingly, the claimed subject matter is both novel and requires an inventive step over Cirone.

In addition, Applicant submits that the amended claims meet the unity of invention requirements of 37 C.F.R. § 1.475(b)(3), since they relate to a product (*i.e.*, T cell composition—claims 16, 17, 28 and 29), a process specially adapted for the manufacture of the product (*i.e.*,

method of making the T cell composition—claims 1, 3-6, 8, 11, 12, 14, 22, and 23), and a use of the product (*i.e.*, method of using the T cell composition—claims 21 and 30-33). In view of the foregoing, Applicant submits that the claims of Groups **I, II, and IV**, which relate to claims **1, 3-6, 8, 11, 12, 14, 16, 17, 21-23, and 28-33** have unity of invention and should all be examined together.

3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

POLSINELLI SHALTON FLANIGAN SUELTHAUS PC

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On behalf of: Teddy C. Scott, Jr., Ph.D.
Registration No. 53,573

By: /Ron Galant, Ph.D./
Ron Galant, Ph.D.
Registration No. 60,558
Customer No. 27148

POLSINELLI SHALTON FLANIGAN SUELTHAUS PC
180 N. Stetson Ave., Suite 4525
Chicago, IL 60601
312.819.1900 (main)
312.602.3955 (E-fax)
312.873.3613 (direct)